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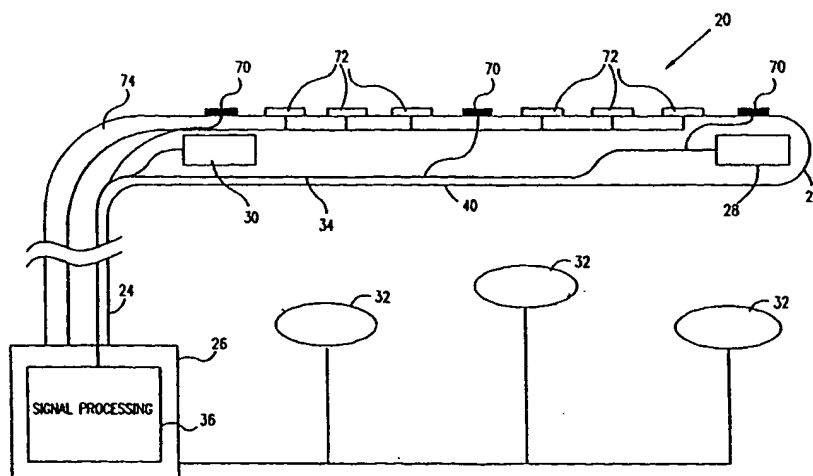


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(21) International Application Number: PCT/IL97/00448 (22) International Filing Date: 31 December 1997 (31.12.97) (30) Priority Data: 60/034,703 3 January 1997 (03.01.97) US 60/034,704 3 January 1997 (03.01.97) US (71) Applicant (for all designated States except US): BIOSENSE INC. [US/US]; Suite 10, 40 Ramland Road, Orangeburg, NY 10962 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): BEN-HAIM, Shlomo [IL/IL]; 101 Yeffe Nof Street, 34454 Haifa (IL). (74) Agents: COLB, Sanford, T. et al.; Sanford T. Colb & Co., P.O. Box 2273, 76122 Rehovot (IL).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BI, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report.	

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(54) Title: CONFORMAL CATHETER



(57) Abstract

This invention is an invasive probe apparatus including a flexible, elongate probe (20), having a distal end (22) for insertion into the body of a subject. The probe includes first and second position sensors (28, 30), fixed in a known relation to the distal end, which generates signals responsive to position coordinates thereof, and at least one contact sensor (70) along a radial surface thereof, which generates signals responsive to the contact of the radial surface with a surface inside the body. The apparatus further includes signal processing circuitry (36), which receives the position/responsive and contact/responsive signals, and processes them to determine the locations of a plurality of points along the length of a portion of the probe in a vicinity of the first and second position sensors.

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CONFORMAL CATHETER**RELATED APPLICATIONS**

This application claims the benefit of U.S. Provisional Patent Applications no. 60/034,703 and 60/034,704, filed January 3, 1997, which are assigned to the assignee of the present patent application and incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to cardiac diagnostic and therapeutic systems, and specifically to invasive medical probes that may be used to map the interior surfaces of the heart.

BACKGROUND OF THE INVENTION

Position-responsive cardiac catheters are known in the art. Such catheters are generally inserted percutaneously and fed through one or more major blood vessels into a chamber of the heart. A position-sensing device in the catheter, typically near the catheter's distal end, gives rise to signals that are used to determine the position of the device (and hence of the catheter) relative to a frame of reference that is fixed either externally to the body or to the heart itself. The position-sensing device may be active or passive and may operate by generating or receiving electrical, magnetic or ultrasonic energy fields or other suitable forms of energy known in the art.

U.S. patent 5,391,199, which is incorporated herein by reference, describes a position-responsive catheter comprising a miniature sensor coil contained in the catheter's distal end. The coil generates electrical signals in response to externally-applied magnetic fields, which are produced by field-generator coils placed outside the patient's body. The electrical signals are analyzed to determine three-dimensional position coordinates of the coil.

PCT patent publication number WO96/05768, filed January 24, 1995, which is assigned to the assignee of the present application and whose disclosure is incorporated herein by reference, describes a position-responsive catheter comprising a plurality of miniature, preferably non-concentric sensor coils fixed in its distal end. As in the 5,391,199 patent, electrical signals generated by these coils in response to an externally-applied magnetic field are analyzed so as to determine, in a preferred embodiment, six-dimensional position and orientation coordinates of the coils.

Multiple position-sensing devices may be placed in a known, mutually-fixed spatial relation at or adjacent to the distal end of a catheter, as described, for example, in PCT patent application no. PCT/IL97/00009, which is assigned to the assignee of the present application and whose disclosure is incorporated herein by reference. This application describes a catheter having a substantially rigid structure at its distal end, to which one or more position sensors are fixed. The sensors are used to determine the position and orientation of the structure,

preferably for use in mapping electrical activity in the heart. Although the structure itself is substantially rigid, the remainder of the catheter is generally flexible, and the position sensors do not provide coordinate information regarding any points on the catheter proximal to the structure.

5 PCT publication WO95/04938, which is also incorporated herein by reference, describes a miniature magnetic field sensor coil and method of remotely determining the coil's location. The sensor coil may be used to determine the spatial configuration or course of flexible
10 endoscope within the body of a subject in one of two ways: (1) By passing the coil through an internal lumen of the endoscope, for example, the endoscope's biopsy tube, and externally tracking the coil's location while the endoscope is held stationary, or (2) By distributing a
15 plurality of the coils, preferably about a dozen, along the length of the endoscope and determining all of the coils' locations. The position coordinates determined with respect to each location of the coil (when a single coil is used) or to all the coils (when the plurality of coils are used) are taken together to interpolatively reconstruct the spatial configuration of the endoscope within the intestines of the subject, for example, and thereby estimate the
20 corresponding spatial configuration of the intestines.

The accuracy of this endoscope in estimating the spatial configuration of the intestines depends on having a relatively large number of position measurements and/or of coils. Passing
25 the coil (or other sensor element) through a lumen in the endoscope is time consuming and physically not practical for use in thin probes, such as cardiac catheters that must be passed through blood vessels. Using a large number of coils, however, undesirably increases the weight and cost of the catheter and reduces its flexibility.

U.S. patent 5,042,486, whose disclosure is further incorporated herein by reference, describes a method of locating a catheter within the body of a subject, generally within a blood
30 vessel, by tracking the position of an electromagnetic or acoustic transmitter or receiver in the tip of the catheter. The position readings are registered with a previously acquired X-ray image of the blood vessel. This method is practical, however, only when the catheter is moving within a vessel or other physiological structure that defines a narrow channel within which the catheter's movement is constrained.

35 PCT publication WO 92/03090, whose disclosure is also incorporated herein by reference, describes a probe system, such as an endoscope, including sensing coils mounted at spaced positions along the probe. An array of antennas in a vicinity of the probe are driven by AC electrical signals, so as to induce corresponding voltage signals in the sensing coils. These signals are analyzed to determine three-dimensional coordinates of the coils. The locations of points along the probe, intermediate a pair of the sensing coils, may be determined by interpolation between the respective coordinates of the coils.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a flexible catheter, for insertion into a cavity in the body of a subject, wherein the catheter curves to conform to an inner surface of the cavity, and the course and/or position of the catheter within the cavity are determined using
5 sensors fixed to the catheter.

It is a further object of the present invention to provide a method of determining the course of the catheter within the body.

In one aspect of the present invention, the course of the catheter may be determined within body cavities, in which the catheter is free to move in three dimensions, and not only
10 within constraining lumens as in the prior art.

It is another object of the present invention, to provide catheters for insertion into a chamber of the subject's heart, for purposes of diagnostic mapping and/or therapeutic treatment in the interior of the chamber, along with methods for determining the course of the distal end of the catheter inside the heart chamber.

15 It is still a further object of the present invention to provide a method of therapeutic treatment of the heart using the catheter.

In preferred embodiments of the present invention, a flexible catheter, having a distal end for insertion into a cavity within the body of a subject, comprises first and second position sensors, fixed in a known relation to one another and to the distal end. The position sensors
20 generates signals responsive to position coordinates thereof. The position-responsive signals are processed jointly to determine the positions of a plurality of points along the length of the catheter, inside the subject's body.

Most preferably, at least one of the position sensors comprises a plurality of magnetic-field-responsive coils, as described in the above-mentioned PCT publication WO96/05768,
25 which enables six-dimensional position and orientation coordinates of the sensor to be determined. The other of the position sensors preferably comprises a similar plurality of coils, or, alternatively, it may comprise a single coil, as described in the above-mentioned 5,391,199 patent. Further alternatively, any suitable position sensors known in the art may be used, such as electrical, magnetic or acoustic sensors, as long as the three-dimensional position
30 coordinates of both the sensors and the three-dimensional orientation coordinates of at least one of the sensors can be determined from the sensor signals. The coordinates of the first and second sensors are determined and taken together with other, known information pertaining to curvature of the catheter intermediate the first and second sensors, as will be described below, to find the positions of a plurality of points along the length of the catheter in a vicinity of the
35 first and second sensors.

In preferred embodiments of the present invention, the catheter is fed forward into a cavity of the body, for example, a chamber of the heart, the portion of the catheter intermediate the first and second position sensors is pressed against an inner wall of the cavity. Preferably,

the catheter includes, along its length, one or more contact sensors, for example, pressure or proximity sensors, as are known in the art, for verifying that the catheter is in contact with or in sufficiently close proximity to the wall. The known coordinates of the first and second position sensors are then taken together with known features of the internal topography of the cavity to
5 determine the curvature of the catheter and the positions of the plurality of points therealong. The topographical features may be known, for example, based on a previously- or simultaneously-acquired ultrasound or X-ray image, or determined using other methods known in the art. Preferably, the catheter is constructed so as to exert a generally uniform force per unit length against the inner wall of the cavity, so that in determining the curvature of the
10 catheter, deformation of the wall is assumed to be minimized.

In some preferred embodiments of the present invention, the catheter includes one or more bend sensors, which generates signals responsive to a bend radius of the catheter in a vicinity thereof, and which signals are processed to determine a radius of curvature of the catheter. These embodiments are described in U.S. Provisional Patent Application no.
15 60/034,703, which is assigned to the assignee of the present patent application, and whose disclosure is incorporated herein by reference. The radius of curvature thus determined is used in finding the positions of the plurality of points along the catheter.

In some preferred embodiments of the present invention, the catheter includes physiological sensors, for example, electrophysiological sensing electrodes, spaced along its
20 length. These sensors are preferably used to generate a map of physiological activity as a function of position within the body cavity.

In further preferred embodiments of the present invention, the catheter includes therapeutic devices at some or all of the plurality of points along its length. In one of these preferred embodiments, for example, the therapeutic devices comprise RF ablation electrodes,
25 which are placed along a desired path against the endocardium by appropriately positioning the catheter, using the position and bend sensors, and are then activated to ablate heart tissue along this path. This method can be used in treating various conduction defects within the heart, including performing "maze procedures," as are known in the art, for alleviating atrial fibrillation.

Preferably, such therapeutic methods using the catheter are preceded by mapping the interior of the body cavity, such as the chamber of the heart, using either physiological sensors on the catheter, as described above, or imaging methods known in the art. The course of the catheter within the cavity, which is determined based on readings of the position and bend sensors, may then be registered with a map of the cavity, so as to ensure that the therapy is
30 administered along the desired path.

In one such preferred embodiment, the RF ablation electrodes also serve as electrophysiological sensing electrodes when they are not being used for tissue ablation. The signals received from the electrodes are preferably analyzed and used to map electrical activity,

as described above, and/or to ascertain that the electrodes are suitably positioned, before performing the ablation.

While preferred embodiments of the present invention are generally described herein with reference to two position sensors, it will be appreciated that the inventive principles that they embody may be similarly applied to catheters, or to other probes, having a larger number of position sensors. Preferably, however, the number of such sensors is held to the minimum needed to achieve the desired accuracy of determination of the plurality of points along the length of the catheter, generally along the portion of the catheter adjacent the distal end thereof.

It will also be appreciated that although the preferred embodiments described herein make reference to catheters, and particularly to intracardiac catheters, it will be appreciated that the principles of the present invention may similarly be applied to other types of flexible medical probes, such as endoscopes.

There is therefore provided, in accordance with a preferred embodiment of the present invention, invasive probe apparatus including:

a flexible, elongate probe, having a distal end for insertion into the body of a subject, and including:

first and second position sensors, fixed in a known relation to the distal end, which generate signals responsive to position coordinates thereof; and

at least one contact sensor along a radial surface thereof, which generates signals responsive to contact of the radial surface with a surface inside the body; and signal processing circuitry, which receives the position-responsive and contact-responsive signals and processes them to determine the locations of a plurality of points along the length of a portion of the probe in a vicinity of the first and second position sensors.

There is further provided, in accordance with another preferred embodiment of the present invention, a method for determining the course of an elongate, flexible probe inside the body of a subject, including:

bringing the probe into contact with a surface inside the body having known topographical features, along a portion of the length of the probe;

finding position coordinates of first and second points on the portion; and

registering the course of the portion with the features, using the position coordinates of the first and second points.

There is additionally provided, in accordance with a preferred embodiment of the present invention, a method for mapping electrical activity in the heart of a subject, including:

inserting an elongate, flexible probe into the heart;

determining the course of the probe inside the heart, according to the method described above; and

receiving electrical signals from heart tissue adjacent to the probe.

Moreover, in accordance with still another preferred embodiment of the present invention, there is provided a method for invasive therapeutic treatment of the heart of a subject, including:

- inserting an elongate, flexible probe into the heart;
- 5 determining the course of the probe inside the heart, according to the method described above; and
- ablating heart tissue adjacent to the probe.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings in which:

10

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of a conformal catheter system, in accordance with a preferred embodiment of the present invention; and

Fig. 2 is a schematic, partly sectional illustration showing the catheter of Fig. 1 inserted into a human heart, in accordance with a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which schematically illustrates a conformal catheter 20, in accordance with a preferred embodiment of the present invention, inserted into the heart of a subject, and a proximal end 24, which is coupled to a control console 26.

5 Adjacent to distal end 22, catheter 20 includes a first position-sensing element 28 and, proximal thereto, a second position-sensing element 30. Elements 28 and 30 define a generally distal portion 40 of catheter 20 therebetween. Preferably, each of elements 28 and 30 comprises three substantially orthogonal, non-concentric coils, as described in PCT publication WO96/05768, which generate signals responsive to magnetic fields applied by field generators
10 32. These signals are conveyed via wires 34 to signal processing and computing circuitry 36 in console 26, which preferably also provides driver and control signals to generators 32. Circuitry 36 analyzes the signals, as further described in the PCT publication, in order to determine the six-dimensional translational and orientational coordinates of elements 28 and 30 in relation to a frame of reference established by generators 32.

15 Fig. 2 schematically illustrates the insertion of catheter 20 into right atrium 62 of a human heart 60, in accordance with a preferred embodiment of the present invention. The curvature of portion 40 of catheter 20 is determined substantially by the curvature of an inner wall 64 of atrium 62 against which the catheter is brought to bear, in response to axial force exerted from the proximal end of the catheter.

20 The shape of inner wall 64 and a desired course of portion 40 against the wall are preferably known in advance of inserting catheter 20 into atrium 62. The shape and desired course may be derived from images of heart 60 acquired by any means known in the art, such as ultrasound, X-ray, or other imaging modality. Alternatively, the shape and desired course may be found by mapping the interior of heart 60, as described in the above-mentioned PCT
25 patent application PCT/IL97/00009 or in U.S. patent application no. 08/476,200, filed June 7, 1995, which are assigned to the assignee of the present invention, and whose disclosures are incorporated herein by reference, or by other mapping methods known in the art. Three-dimensional position coordinates of elements 28 and 30 and three dimensional orientation
30 coordinates of at least one of the elements are determined and are referred to the known shape, in order to ascertain that portion 40 of catheter 20 is arrayed along the desired course in contact with wall 64. Preferably, portion 40 is sufficiently and homogeneously flexible, so as to exert a uniform force per unit length against wall 64. Thus, in determining the curvature of the portion, deformation of the wall is assumed to be minimized.

Referring again to Fig. 1, catheter 20 preferably includes optional pressure sensors 70
35 and ablation electrodes 72 (which are omitted in Fig. 2 for clarity). The output signals of pressure sensors 70 are coupled via wires 34 to signal processing circuitry 36, which analyzes the signals to determine whether catheter 20 is in contact along the length of portion 40 with wall 64. If the output signals of all of sensors 70 indicate that the sensors are at roughly equal

respective positive pressures, due to force exerted between portion 40 and wall 64, it can then be assumed that portion 40 is conforming to the shape of the wall, which has been previously determined as described above. Proximity sensors or other sensors known in the art may be used in place of pressure sensors 70. It will be understood that there may be a greater or lesser number of pressure sensors or other sensors on catheter 20 than the three sensors 70 shown in Fig. 1, or no such sensors at all.

Ablation electrodes 72 receive RF energy, under the control of a physician or other user of catheter 20, from console 26 via wires 74, so as to ablate a row of desired sites that are adjacent to the electrodes on wall 64. Catheter 20 may include more or fewer ablation electrodes 72 than the six electrodes shown in Fig. 1, or no ablation electrodes. Other ablation devices, known in the art, may also be used.

Pressure sensors 70 and ablation electrodes 72 on catheter 20 are useful in performing certain therapeutic procedures. For example, catheter 20 as shown in Figs. 1 and 2 may be used to perform a "maze" procedure, known in the art for treatment of atrial fibrillation (AF). In accordance with the present invention, the physician determines a linear or non-linear course along atrial wall 64 that should be ablated in order to interrupt abnormal conduction paths in the heart tissue that cause AF. Catheter 20 is inserted into heart 60 and portion 40 thereof is positioned along this course, in contact with wall 64, as described above. Electrodes 72 are then activated to ablate the entire course simultaneously, with greater speed and accuracy than are afforded by present methods of performing the maze procedure. Multiple courses may desirably be determined, and portion 40 of catheter 20 may be re-positioned and operated to ablate each of the courses in succession.

In other preferred embodiments of the present invention, sensing electrodes may be used in place of ablation electrodes 72, in order to map electrical activity within the heart tissue. A map of the interior of heart 60 that is generated using this method may then serve to guide therapeutic procedures, such as the "maze" procedure described above.

More generally speaking, while the preferred embodiments of the present invention have been described herein with reference to two position-sensing elements 28 and 30, it will be appreciated that for some applications, catheter 20 may preferably comprise a greater number of position sensors and/or of bend sensors. Such additional sensors may be particularly useful when a portion of the length of the catheter must be tracked within a convoluted passage, or when the catheter is brought to bear against and is desired to conform to a convoluted surface within a body cavity. Preferably, however, the number of such sensors is held to the minimum needed to achieve the desired accuracy of determination of the plurality of points along the length of the catheter.

Furthermore, in other preferred embodiments of the present invention, other devices and methods may be used to determine the curvature of portion 40 of catheter 20, for example,

as described in the above-mentioned U.S. provisional patent application no. 60/034,703 and incorporated herein by reference.

5 It will be appreciated that although the preferred embodiments described above make reference to intracardiac catheter 20, the principles of the present invention may similarly be applied to other types of catheters, as well as other flexible medical probes, such as endoscopes.

It will also be appreciated that the preferred embodiments described above are cited by way of example, and the full scope of the invention is limited only by the claims.

CLAIMS

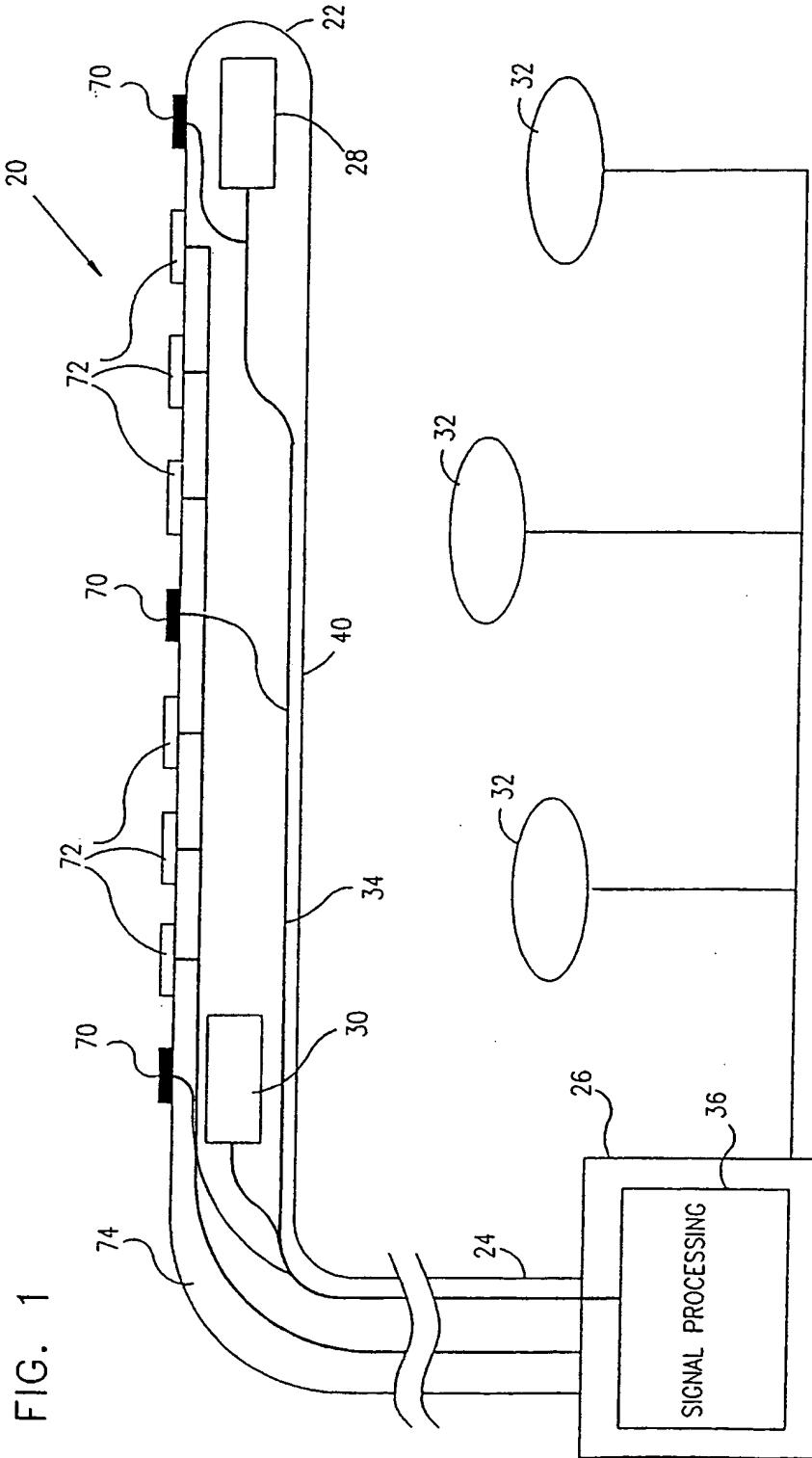
1. Invasive probe apparatus comprising:
a flexible, elongate probe, having a distal end for insertion into the body of a subject,
comprising:
 - 5 first and second position sensors, fixed in a known relation to the distal end,
which generate signals responsive to position coordinates thereof; and
at least one contact sensor along a radial surface thereof, which generates
signals responsive to contact of the radial surface with a surface inside the body; and
signal processing circuitry, which receives the position-responsive and contact-
10 responsive signals and processes them to determine the locations of a plurality of points along
the length of a portion of the probe in a vicinity of the first and second position sensors.
2. Apparatus according to claim 1, wherein at least one of the position sensor comprises at
least one coil, which generates signals responsive to an externally-applied magnetic field.
3. Apparatus according to claim 1, wherein the signal processing circuitry determines six-
15 dimensional position and orientation coordinates of at least one of the position sensor.
4. Apparatus according to claim 1, and comprising a bend sensor.
5. Apparatus according to claim 1, wherein the at least one contact sensor comprises a
pressure sensor.
6. Apparatus according to claim 1, wherein the at least one contact sensor comprises a
20 proximity sensor.
7. Apparatus according to any of the preceding claims, and comprising an ablation device
disposed along the length of the portion of the probe.
8. Apparatus according to claim 7, wherein the ablation device comprises at least one RF
electrode, radially disposed along the length of the portion.
- 25 9. Apparatus according to claim 8, wherein the at least one RF electrode comprises a
longitudinal row of electrodes.
10. Apparatus according to any of claims 1-6, and comprising a physiological sensor
disposed along the length of the portion of the probe.
11. A method for determining the course of an elongate, flexible probe inside the body of a
30 subject, comprising:
bringing the probe into contact with a surface inside the body having known
topographical features, along a portion of the length of the probe;
finding position coordinates of first and second points on the portion; and

registering the course of the portion with the features, using the position coordinates of the first and second points.

12. A method according to claim 11, and comprising determining the locations of a plurality of points along the length of the portion of the probe, in contact with the surface inside the body.
13. A method according to claim 11, wherein finding position coordinates comprises finding six-dimensional translation and orientation coordinates.
14. A method according to claim 11, wherein registering the course of the portion with the features comprises measuring a bending angle of the probe.
15. A method according to claim 11, and comprising measuring a pressure exerted by the probe on the surface so as to verify the registration of the course of the portion of the probe.
16. A method according to claim 11, and comprising measuring a proximity of a point along the length of the probe to the surface so as to verify the registration of the course of the portion of the probe.
17. A method according to any of claims 11-16, wherein bring the probe into contact with the surface of the body comprises bringing the probe into contact with a wall of a chamber of the heart of a subject, and wherein registering the course of the probe with the features comprises registering the course of the probe with the features of the wall.
18. A method for mapping electrical activity in the heart of a subject, comprising:
inserting an elongate, flexible probe into the heart;
determining the course of the probe inside the heart, according to the method of claim 17; and
receiving electrical signals from heart tissue adjacent to the probe.
19. A method for invasive therapeutic treatment of the heart of a subject, comprising:
inserting an elongate, flexible probe into the heart;
determining the course of the probe inside the heart, according to the method of claim 17; and
ablating heart tissue adjacent to the probe.
20. A method according to claim 19, wherein ablating heart tissue comprises ablating tissue at a row of sites longitudinally disposed along the course of the probe.
21. A method according to claim 20, wherein bringing the probe into contact with the features comprises bending a portion of the probe into a non-linear shape against the features, and wherein ablating tissue at the row of sites comprises ablating tissue at sites disposed in non-linear mutual orientation along the bent portion of the probe.

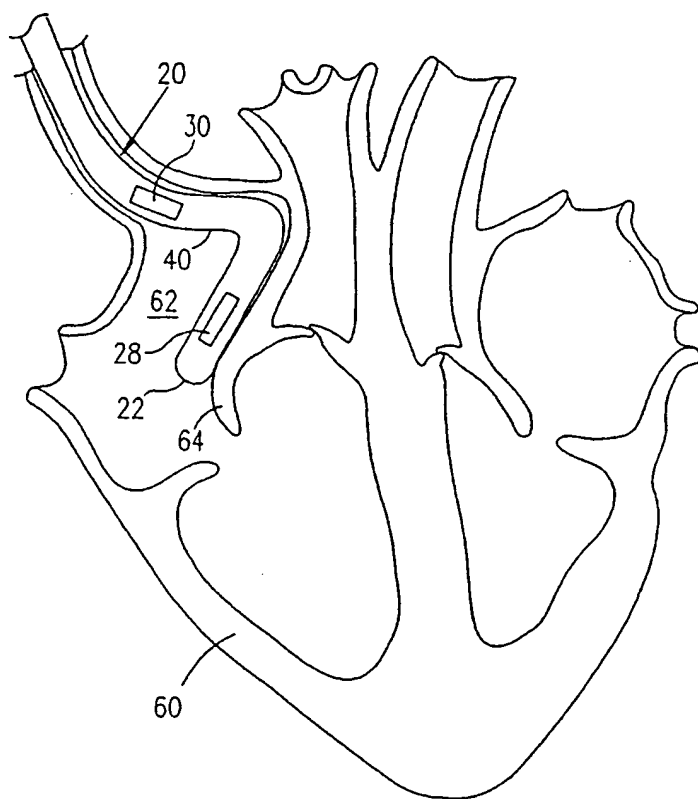
22. A method according to claim 19, and comprising receiving electrical signals from the heart tissue adjacent to the probe.
23. A method according to claim 22, wherein receiving the electrical signals comprises receiving signals from electrodes that are used in ablating the heart tissue adjacent to the probe.

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2/2

FIG. 2



INTERNATIONAL SEARCH REPORT

International application No.

PCT/L97/00448

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/05

US CL :128/899; 600/424, 508; 607/122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/117,424,508; 128/899; 607/122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,273,025 A (SAKIYAMA et al) 28 December 1993, entire document	1-23
Y	US 4,982,725 A (HIBINO et al) 08 January 1991, entire document.	1-10, 12, 14, 15, 17-23
Y	US 5,558,073 A (POMERANZ et al) 24 September 1996, entire document	7-9, 18-22



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

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☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

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